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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,513	06/22/2006	John Brownlie	ERP02.003APC	3443

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EXAMINER

BLUMEL, BENJAMIN P

ART UNIT	PAPER NUMBER
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1648

NOTIFICATION DATE	DELIVERY MODE
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12/19/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/522,513	Applicant(s) BROWNLIE ET AL.	
	Examiner BENJAMIN P. BLUMEL	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 128-131, 134-136, 144, 164 and 165 is/are pending in the application.
- 4a) Of the above claim(s) 144 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 128-131, 134-136, 164 and 164 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/2/05 & 2/13/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of group XVIII and the required species in the reply filed on September 2, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim 144 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on September 2, 2008.

Claims 128-131, 134-136, 164 and 165 are examined on the merits.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on December 2, 2005 and February 13, 2008 were filed. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 131 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The above claim states "...is listed in Figure 4; and comprising at least one of the canine respiratory coronavirus (CRCV)-specific amino acids listed in Table 1...". However, it is unclear which S protein these residues pertain to since there are fragments and variations of the CRCV S protein. Are these proteins actually fragments of at least 103 residues? Does the start of the S protein include the N-terminus or does it start with a residue closer to the C-terminus (i.e., the last 103 residues of the S protein)?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 128-131, 134-136, 164 and 165 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an immunogenic composition based on an attenuated/inactivated Canine Respiratory Coronavirus (CRCV), does not reasonably provide enablement for a vaccine for such a virus. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Nature of the invention/Breadth of the claims. The claims are drawn to a vaccine for dogs based on Canine Respiratory Coronavirus (CRCV). The CRCV has an S protein with at least 75% identity with that of an S protein from CRCV. The coronavirus is

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either attenuated or inactivated and may also be combined with an acceptable adjuvant.

The vaccine composition may also contain an agent capable of raising an immune response in a dog to: canine parainfluenza virus (CPIV); or canine adenovirus type 2 (CAV-2); or canine herpesvirus (CHV); or *Bordetella bronchiseptica* (*B. bronchiseptica*).

For purposes of examination, it is noted that CRCV is also referred to as CRCoV, CCoV and CCV.

State of the prior art/Predictability of the art. The art of vaccine development towards canine respiratory coronavirus does not acknowledge that one exists. An American Veterinary Medical Association (AVMA) summary of emerging canine viruses published in April, 2008 reported that no vaccine was available for CRCoV. In addition, Decaro and Buonavoglia (Veterinary Microbiology, 2008) state that no vaccine is available for CRCV exposure and that such a vaccine should be developed if the virus can be directly linked to CIRDC (canine infectious respiratory disease). Moreover, Erles and Brownlie (who are co-inventors) (Veterinary Clinics of North America: Small animal practice, 2008) also reviewed the epidemiology of CRCV and they stated that no known treatment was available, particularly that no vaccine has been developed for CRCV (see page 822).

Working examples. No working example is disclosed in the specification. Vaccine efficacy is evidenced by challenge experiments in acceptable animal models, however no such evidence has been submitted in this application.

Guidance in the specification. The specification provides guidance for using the attenuated/inactivated coronavirus as a vaccine for dogs.

Amount of experimentation necessary. Additional research is required in order to determine how effective a vaccine for CRCV based on an attenuated/inactivated CRCV that expresses a S protein that has at least a 75% amino acid homology with that of the S protein from CRCV.

For the reasons discussed above, it would require undue experimentation for one skilled in the art to use the claimed methods.

Claim Objections

Claim 131 is objected to because of the following informalities: the claim recites, "...is listed in Figure 4; and comprising at least one of the canine respiratory coronavirus (CRCV)-specific amino acids listed in Table 1;...". However, since Figure 4 is a specific amino acid sequence and Table 1 requires certain amino acids, claim 131 must be amended to recite, "...is SEQ ID NO: 4; and comprising at least one of the canine respiratory coronavirus (CRCV)-specific amino acids from the group consisting of 103V, 118V, 166D...;..." Appropriate correction is required.

Claim 128 is objected to because of the following informalities: since the acronym "CRCV" is not as readily recognized as "DNA", it is suggested that claim 128 be amended to recite, "...Canine Respiratory Coronavirus (CRCV)...". Appropriate correction is required.

Claims 128-131, 134-136, 164 and 165 are objected to because of the following informalities: Claim 128 recites, "A vaccine composition for vaccinating dogs comprising a coronavirus...", however, is the vaccine intended for protecting a dog from coronaviruses or some other pathogen since the preamble of the claim only recites a

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vaccine for dogs based on coronaviruses being employed. Appropriate correction is required.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN P. BLUMEL whose telephone number is (571)272-4960. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stacy B Chen/
Primary Examiner, Art Unit 1648

/BENJAMIN P BLUMEL/
Examiner
Art Unit 1648